IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
WACO DIVISION

W. H. WALL FAMILY HOLDINGS, LLLP, **Plaintiff,** **v.** **PHILIPS IMAGE GUIDED THERAPY CORPORATION,** **Defendant.**	**Jury Trial Demanded** **Civil Action No. 6:21-cv-20**

COMPLAINT FOR PATENT INFRINGEMENT

Pursuant to the Federal Rules of Civil Procedure, W. H. Wall Family Holdings, LLLP ("WFH") files its Complaint for Patent Infringement against Defendant Philips Image Guided Therapy Corporation ("Defendant"), showing this Court as follows.

NATURE OF THE ACTION

1. WFH is the owner by assignment of U.S. Patent No. 6,974,475 (the "'475 Patent"). [A true and correct copy of the '475 Patent is attached hereto as Exhibit 1]. The '475 Patent is a pioneering patent in the field of medical stent technology, with a priority date of December 8, 1987, and a term ending on December 12, 2022.

2. This action arises out of Defendant's infringement of certain claims of the '475 Patent.

THE PARTIES

3. Plaintiff WFH is a limited liability limited partnership organized and existing under the laws of the state of Georgia. WFH's principal place of business is in Stone Mountain, Georgia.

4. Upon information and belief, Defendant was founded in 2000.

5. Upon information and belief, Defendant is a corporation organized and existing under the laws of the state of Delaware, with its principal place of business in Andover, Massachusetts. Upon information and belief, Defendant further maintains an office, and regularly does business, in the State of Texas, including maintaining an office in the Western District of Texas.

6. Upon information and belief, Defendant acquired Intact Vascular Corporation during the third quarter of 2020.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States, namely 35 U.S.C. §§ 271, 281, and 284-285, among others.

8. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over Defendant.

10. Venue is proper in this judicial district pursuant to 28 U.S.C. §1400(b).

ATHEROSCLEROSIS AND STENT TECHNOLOGY

11. Atherosclerosis is a buildup of cholesterol and fatty deposits, i.e., plaque, that narrows or blocks blood flow within arteries. Coronary artery disease ("CAD") is a form of atherosclerosis in which plaque narrows or blocks blood flow in the arteries supplying the heart. Similarly, peripheral artery disease ("PAD") is a form of atherosclerosis in which plaque narrows or blocks blood flow in arteries not leading to heart, such as those leading to an arm or leg.

12. These blockages, or atherosclerotic lesions, are frequently treated with percutaneous transluminal intervention (PTI).

13. Initial PTI procedures included coronary angioplasty, first performed by Andreas Greuntzig in 1977.

14. During an angioplasty procedure, a specially designed catheter with a tiny balloon is carefully guided through the artery to the blockage, then inflated to widen the opening and increase blood flow within the artery. Although largely effective, angioplasty occasionally resulted in a number of adverse effects, including damage to the artery or post-operative closure of the artery.

15. Over time, doctors have recognized that these adverse effects from treating atherosclerosis with angioplasty alone may be mitigated by using stents in

conjunction with angioplasty. A stent is a wire mesh tube or "scaffold" that is permanently implanted in the artery to keep the artery open and can be combined with angioplasty to treat atherosclerosis. The stent helps support the inner wall of the artery following the PTI procedure.

16. Generally speaking, there are two types of stents: (1) balloon-expandable stents and (2) self-expandable stents.

17. Balloon-expandable stents are biased in a collapsed position and the surgeon uses an angioplasty balloon to expand and set the stent within the arterial segment containing the blockage. With balloon-expandable stents, a balloon is inflated to compress the plaque that has built up inside the artery against the artery's wall. The stent, which was carried on the deflated balloon, expands when the balloon expands, and is pushed into place in the artery. The balloon is then deflated and removed along with the catheter, leaving the stent in place.

18. Self-expandable stents are biased in an expanded position but are constrained within a delivery mechanism until placement, when the surgeon removes the constraining device allowing expansion of the stent. With self-expandable stents, the surgeon may also utilize balloon angioplasty to expand the artery prior to stent placement.

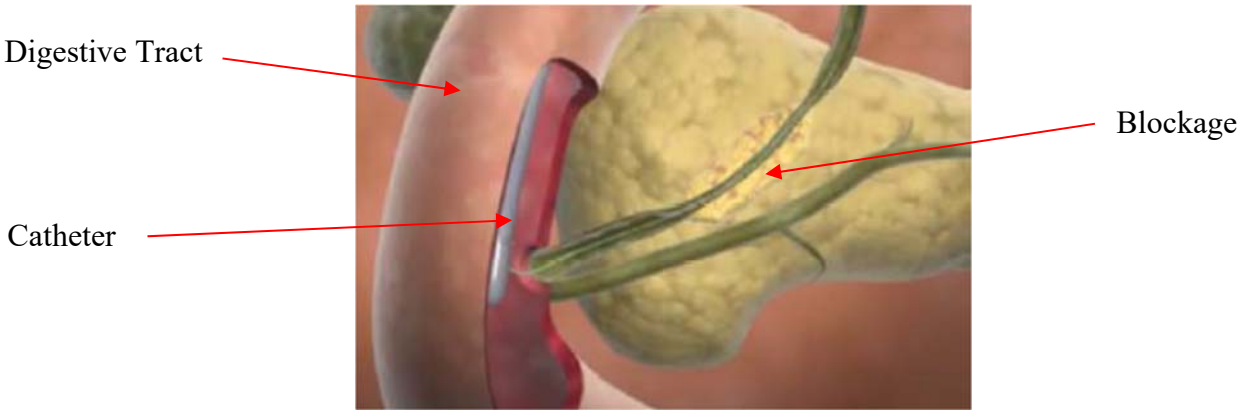
OTHER LUMINAL OBSTRUCTIONS AND STENT TECHNOLOGY

19. Other lumens in the human body may also become obstructed through either malignant or benign growths or injury, including bile ducts.

20. The liver produces bile which aids digestion of fats. The bile flows through a series of small tubes (ducts) that drain into one large duct called the common bile duct, which then empties into the duodenum. If a bile duct becomes blocked, the bile cannot drain normally and backs up in the liver. Signs of blocked bile ducts include jaundice (yellowing of the skin).

21. Biliary stenting is a procedure widely used to remedy biliary obstructions. A biliary stent is a small, expandable mesh tube or "scaffold" usually made of metal or plastic that is placed at the location of the obstruction and expanded to provide a passage through the obstruction to increase the flow of bile through the duct. The stent helps support the inner wall of the lumen.

22. During placement of a biliary stent, a surgeon carefully guides a catheter containing the stent through the digestive tract to the blockage, where the stent is expanded to increase the flow of bile through the duct.



23. Alternatively, biliary stents may also be placed through the skin, utilizing a needle and guidewire.

THE '475 PATENT

24. In 1981, while he was working as a visiting clinical professor at Emory Dental School, Dr. Wall became acquainted with Dr. Greuntzig, who had recently joined the Emory faculty. Dr. Wall studied the balloon angioplasty therapy pioneered by Dr. Greuntzig and concluded that arterial blockage would likely return in patients—a condition referred to as restenosis. Dr. Wall considered this issue and began working on ideas to address this problem. Initially, he tried to develop an ultrasound method to remove the blockage.

25. After experimenting with this idea, Dr. Wall concluded that this method was not a viable solution. On or about October 15, 1984, he conceived the invention of inserting a sleeve into an artery following an angioplasty procedure. The sleeve would then effectively hold open the artery and prevent restenosis. Dr.

Wall filed a disclosure document with the USPTO in December 1984, and filed patent application no. 07/129,834 (the "'834 Application") on December 8, 1987.

26. The '834 Application duly issued as the '475 Patent on December 13, 2005.

27. WFH is the owner by assignment of all rights in the '475 Patent.

28. The '475 Patent relates generally to a prosthesis that can be inserted into a bodily lumen while in a collapsed position, and then expanded in order to prevent restenosis in the lumen. WFH has the right to enforce the '475 Patent and to recover all damages available under law.

29. As an example, Claim 39 of the '475 Patent provides:

> 39. A stent for placement into a narrowed opening of a lumen of the human body and for maintaining at least a minimum opening within the lumen, said stent comprising:
>
> a radially collapsible sleeve formed in a mesh and a coating applied thereto,
>
> said sleeve defining a plurality of openings throughout the mesh to allow tissue to grow therethrough, and
>
> said mesh being biased toward either its collapsed position or its expanded position.

30. The ’475 Patent, and Dr. Wall’s invention described therein, have been the subject of numerous articles, including a 2006 article in the Wall Street Journal, entitled “Will Stent Makers Fight Dentist’s Patent Tooth and Nail?”

31. In 2008, Boston Scientific Corp. filed a well-publicized declaratory judgment action, seeking to invalidate the ’475 Patent.

32. Since 2008, press articles have discussed settlements of WFH’s claims of infringement of the ’475 Patent with a number of medical device manufacturers such as Boston Scientific, Johnson & Johnson, and Abbott Laboratories, including WFH’s settlement in 2020 with Celonova.

33. Defendant has had knowledge—or, with reasonable diligence would have had knowledge—of the ’475 Patent since at least 2016.

DEFENDANT’S TACK (6F) SYSTEM

34. In 2019, the U.S. Food and Drug Administration (the “FDA”) issued a Pre-Market Approval for Defendant’s Tack Endovascular System® (6F) (the “Tack 6(f) System”), stating the product

> is indicated for use in the superficial femoral and proximal popliteal arteries ranging in diameter from 3.5mm to 6.0mm for the repair of post percutaneous transluminal balloon angioplasty (PTA) dissection(s).

[April 11, 2019, Pre-Market Approval for the Tack Endovascular System® (6F), p. 1 (a copy of which is attached hereto as Exhibit 2)].

35. The Tack (6F) System comprises a series of 6 self-expanding nitinol stents loaded onto a delivery catheter.

[Intact Vascular, INSTRUCTIONS FOR USE (IFU), THE TACK ENDOVASCULAR SYSTEM® (6F) (LBL 1002 Rev. E) (the "TACK 6F IFUS"), p. 1 and FIG. 1, (a true and correct copy of which is attached hereto as Exhibit 3)].

36. The nitinol stents in the Tack (6F) System comprise a radially expandable sleeve formed in a mesh with, upon information and belief, a coating applied thereto through passivation, such as through oxidation, or electropolishing.

37. The nitinol stents in the Tack (6F) System further comprise a sleeve defining a plurality of openings throughout the mesh to allow tissue to grow therethrough.

38. The TACK 6F IFUS further explain that a delivery catheter is used to position the system's nitinol stent(s) in a lumen. [Ex. 3, p. 9]. Once properly positioned, one or more of the nitinol stents in the Tack 6F System is expanded by removal of a constricting covering sheath. [Ex. 3, p. 9-10; Fig. 1]. Once each nitinol stent in the Tack 6F System is fully expanded, the deployment is completed by removal of the delivery catheter. [Ex. 3, p. 10].

39. Each nitinol stent in the Tack 6F System thus further comprises a mesh that is biased towards its open position but constrained in closed position by a constricting covering sheath until expanded by the surgeon.

DEFENDANT'S TACK (4F) SYSTEM

40. In 2020, the U.S. Food and Drug Administration (the "FDA") also issued a Pre-Market Approval for Defendant's Tack Endovascular System® (4F, 1.5-4.5mm) (the "Tack 4F System"), stating the product

> is indicated for use in mid/distal popliteal, tibial and peroneal arteries ranging in diameter from 1.5 mm to 4.5 mm for the repair of post percutaneous transluminal balloon angioplasty (PTA) dissection(s).

[April 11, 2020, Pre-Market Approval for Defendant's Tack Endovascular System® (4F, 1.5-4.5mm), a copy of which is attached hereto as Exhibit 4, at p. 1].

41. The Tack 4F System comprises a series of 4 nitinol stents loaded onto a delivery catheter.

[Intact Vascular, INSTRUCTIONS FOR USE (IFU), THE TACK ENDOVASCULAR SYSTEM® (4F, 1.5-4.5mm) (LBL 1502-01 Rev. C, 09/2019) (the "TACK 4F IFUs"), p. 3 (a true and correct copy of which is attached hereto as Exhibit 5)].

42. The nitinol stents in the Tack (4F) System comprise a radially expandable sleeve formed in a mesh with, upon information and belief, a coating applied thereto through passivation, such as through oxidation, or electropolishing.

43. The nitinol stents in the Tack (4F) System further comprise a sleeve defining a plurality of openings throughout the mesh to allow tissue to grow therethrough.

44. The TACK 4F IFUS further explain that a delivery catheter is used to position the system's nitinol stent(s) in a lumen. [Ex. 5, p. 9]. Once properly positioned, one or more of the nitinol stents in the Tack 4F System is expanded by removal of a constricting covering sheath. [Ex. 5, p. 9-10; Fig. 1]. Once each nitinol stent in the Tack 4F System is fully expanded, the deployment is completed by removal of the delivery catheter. [Ex. 5, p. 10].

45. Each nitinol stent in the Tack 4F System thus further comprises a mesh that is biased towards its open position but constrained in closed position by a constricting covering sheath until expanded by the surgeon.

46. All conditions precedent to the assertion of the claims herein have been satisfied or waived.

COUNT I
DIRECT INFRINGEMENT—'475 PATENT (TACK 6F SYSTEM)

47. WFH incorporates by reference as if fully set forth herein its averments in Paragraphs 1-46, above.

48. As set forth above, the Tack 6F System comprises, literally or through the doctrine of equivalents, each limitation of at least Claim 39 of the '475 Patent.

49. Defendant, or its predecessor-in-interest, has manufactured, sold and offered for sale the Tack 6F Stent within the U.S. since, upon information and belief, at least 2019, in violation of 35 U.S.C. §271, *et seq.*

50. Upon information and belief, including the allegations above showing knowledge and intent, despite having knowledge of the '475 patent and knowledge that the Tack 6F System infringes one or more claims of the '475 patent, Defendant has nevertheless continued its infringing conduct and disregarded an objectively high likelihood of infringement. Accordingly, Defendant's infringing activities relative to the '475 patent have been, and continue to be, willful, wanton, malicious, in bad-faith, deliberate, consciously wrongful, flagrant, characteristic of a pirate, and an egregious case of misconduct beyond typical.

51. WFH has been, and continues to be, damaged by Defendant's infringement of the '475 Patent, in an amount not less than a reasonable royalty, together with interests and costs as fixed by this Court pursuant to 35 U.S.C. §284.

COUNT II

DIRECT INFRINGEMENT—'475 PATENT (TACK 4F SYSTEM)

52. WFH incorporates by reference as if fully set forth herein its averments in Paragraphs 1-46, above.

53. As set forth above, the Tack 4F System comprises, literally or through the doctrine of equivalents, each limitation of at least Claim 39 of the '475 Patent.

54. Defendant, or its predecessor-in-interest, has manufactured, sold and offered for sale the Tack 4F Stent within the U.S. since, upon information and belief, at least 2019, in violation of 35 U.S.C. §271, *et seq.*

55. Upon information and belief, including the allegations above showing knowledge and intent, despite having knowledge of the ’475 patent and knowledge that the Tack 4F System infringes one or more claims of the ’475 patent, Defendant has nevertheless continued its infringing conduct and disregarded an objectively high likelihood of infringement. Accordingly, Defendant’s infringing activities relative to the ’475 patent have been, and continue to be, willful, wanton, malicious, in bad-faith, deliberate, consciously wrongful, flagrant, characteristic of a pirate, and an egregious case of misconduct beyond typical.

56. WFH has been, and continues to be, damaged by Defendant’s infringement of the ’475 Patent, in an amount not less than a reasonable royalty, together with interests and costs as fixed by this Court pursuant to 35 U.S.C. §284.

INJUNCTIVE RELIEF

57. WFH seeks preliminary and permanent injunctions as a result of Defendant’s infringement of the ’475 Patent. WFH is likely to succeed in showing that Defendant infringes the ’475 Patent. Because of that infringement, WFH has suffered an irreparable injury, and the remedies available at law, such as monetary damages, are inadequate to compensate for that injury. Considering the balance of hardships between WFH and Defendant, a remedy in equity is warranted; and the public interest would not be disserved by a permanent or preliminary injunction.

CONCLUSION

58. WFH is entitled to recover from Defendant the damages sustained by WFH as a result of Defendant's wrongful acts in an amount subject to proof at trial, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court.

59. WFH has incurred and will incur attorneys' fees, costs, and expenses in the prosecution of this action. The circumstances of this dispute may give rise to an exceptional case within the meaning of 35 U.S.C. § 285, and WFH is entitled to recover its reasonable and necessary attorneys' fees, costs, and expenses.

JURY DEMAND

60. WFH hereby requests a trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure.

PRAYER FOR RELIEF

61. WFH respectfully requests that the Court find in its favor and against Defendant, entering a judgment in favor of WFH and granting the following relief:

a) Finding that Defendant has infringed the '475 Patent as alleged herein;

b) Requiring an accounting of all damages sustained by WFH as a result of the acts of infringement by Defendant;

c) A preliminary and permanent injunction against Defendant, its subsidiaries, or anyone acting on its behalf from making, using,

selling, offering to sell, or importing any products that infringe the '475 Patent and any other injunctive relief the Court deems just and equitable;

d) Awarding to WFH damages under 35 U.S.C. §284, including not less than a reasonable royalty and up to treble damages;

e) Requiring Defendant to pay WFH pre-judgment and post-judgment interest on the damages awarded;

f) Awarding to WFH the statutory costs of this action;

g) Finding this to be an exceptional case and requiring Defendant to pay to WFH its attorneys' fees and non-statutory costs incurred in this action under 35 U.S.C. §285; and

h) Awarding WFH such other and further relief as this Court deems just and appropriate, premises considered.

This 11th day of January, 2020.

Respectfully submitted,

LOCKE LORD LLP

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